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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,316	04/21/2004	Joel R. Studin	SDF 04-14	5671

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,316	STUDIN, JOEL R.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, Applicant's Arguments/Remarks and the request for extension of time (3 months-granted), all filed 04/12/07 is acknowledged.

Applicant has overcome the following rejection(s): The non-statutory double patenting rejection of claims 1, 5-16, 30 and 31 over claims 1-17 of copending Application No. 10/715,183 has been withdrawn by virtue of the Abandonment of the '183 Application.

Claims 1-16 and 30-32 are pending in this action. Claims 17-29 and 33-54 have previously been cancelled. No claims have been amended herein. Claims 1-16 and 30-32 remain rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d

1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention/(5) The breadth of the claims:

The invention is directed to a method of treating healed wounds so as to prevent or reduce scarring and/or improve the appearance of scars comprising: applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound, thereby preventing or reducing scarring or improving the appearance of a scar.

(2) The state of the prior art:

The prior art teachings provide for methods for delivering drugs on human body surfaces, and drug formulations and delivery systems that can be applied to and then peeled off the skin and/or off compromised human body surfaces after the drug delivery is achieved.

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art:

The unpredictability of the art is high.

(6) The amount of direction or guidance presented:

The specification filed 04/21/05 discloses 'preventing or reducing' scarring by applying a composition comprising a fluid, film-forming carrier, and hardening the carrier into a tangible

membrane. While "treating" or "reducing" scarring may be possible by application of the instant composition, it is unclear to the Examiner as to how application of the instant composition can "*prevent*" scarring. The 'prevention' of scarring would require 'undue' and painstaking experimentation by one of ordinary skill in the art. It is suggested that the term "preventing" in Claims 1 and 30 be deleted.

(7) The presence or absence of working examples:

The working examples are insufficient to establish the method of treating healed wounds to 'prevent' scarring. The examples present "scar-healing" compositions and methods, but do not present "scar-*preventing*" compositions and methods (See for instance, Example 1 – pg. 24 of Specification).

(8) The quantity of experimentation necessary:

The instant invention provides for a method of treating healed wounds so as to prevent or reduce scarring and/or improve the appearance of scars comprising: applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound, thereby preventing or reducing scarring or improving the appearance of a scar. When the above factors are weighed together, it is the position of the Examiner that the instant invention would require 'undue' and painstaking experimentation to arrive at the instant invention to determine which particular combination of components and process steps would be required for 'reducing' scarring with the "prevention" of scar formation being even less probable. Deletion of the term "preventing" would overcome this rejection.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 10-16 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang (US Pat. No. 6,528,086 B2).

The instant invention is drawn to a method of treating healed wounds so as to prevent or reduce scarring and/or improve the appearance of scars comprising: applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound, thereby reducing scarring or improving the appearance thereof.

Zhang ('086) teaches methods and formulations for dermal drug delivery on a human body surface comprising less than solid anesthetic formulations and delivery systems that can be applied to the skin or compromised surfaces and subsequently converted to a soft coherent solid state and then peeled off after the anesthetic effect is achieved (see Abstract); (column 1, lines 9-23). The formulation comprises a topically delivered drug, a conversion agent and a vehicle medium or carrier, wherein the drug is dispersed in the carrier (col. 3, lines 20-22). At the time of application of the formulation to the skin, the formulation is in a less-than-solid phase. At the conclusion of the treatment, the formulation is a coherent, soft solid that can be cleanly peeled from the skin (col. 3, lines 23-29).

The formulation contains active ingredients of topical and local anesthetic agents and systemic circulation and regional tissue drugs of analgesics, hormones and anti-inflammatory agents (col. 14, lines 55-61).

According to Zhang, the topically delivered drug or pharmaceutical can be a single drug, such as a single local anesthetic or a combination of drugs (*i.e.*, eutectic mixture of lidocaine and tetracaine). The drug may be dispersed throughout the formulation in a solid form, dissolved in oil droplets, which are dispersed in the vehicle medium, or in aqueous solution within the vehicle medium. The drug should be capable of transdermal delivery. The vehicle medium facilitates

application of the formulation and delivery of the drug. Permeation enhancers may also be added (col. 3, lines 10-58).

The conversion agent provides the formulation with the ability to change from one phase to another more solid and coherent phase, such as from a liquid or cream to a soft solid. The formulation is applied to a patient's skin in such a way as to form a continuous layer of formulation. When the phase change occurs, the solidified formulation is more easily removed from the patient's skin. The formulation does not leave behind residues or films. Zhang teaches that a unique feature of his invention is that the solid phase is coherent and has certain strength so it can be *peeled off* the body surface as a layer, leaving little residual formulation. The formulation will be flexible and not brittle (see col. 3, line 59 – col. 4, line 9).

Zhang teaches the use of polyvinyl alcohol as an ingredient in the cream formulation of his invention (col. 4, lines 22-32).

Cellulose derivatives are disclosed at column 12, lines 13-25).

Various drugs and pharmaceutical agents can be included in the formulation, such as dermatological agents; drugs for promoting wound healing; drugs for treating warts and moles; drugs for treating ulcerated skin; drugs for treating insect bites and minor cuts; anti-inflammatory agents (e.g., corticosteroids); analgesics (narcotic agents, steroids); vitamins; agents for treating necrotic tissues and dermal ulcers used in debridement (e.g. *collagenase*); hormones and the like (col. 11, lines 16 – col. 14, line 64).

Application techniques of the composition are taught at column 18, lines 12-55. Additionally, Zhang teaches that the formulation may be molded or manipulated so that the

surface being treated is covered by a substantially even layer of the formulation (col. 5, lines 34-37).

The various Tables and examples demonstrate different applications of the invention. For example, Table A (Formulation I) at column 7, shows a formulation comprising a pharmaceutical agent (eutectic mixture), polyvinyl alcohol, glycerol, lecithin, Water Lock® and water in various percentage weights wherein it states that Formulation I should be easy to apply and remove (i.e., in form of cream, paste) when applied to the skin, but should form a solid gel so that it can be easily 'peeled off' the skin without leaving a mess on the skin. Tables B and onwards demonstrate anesthetic formulations comprising mixtures of anesthetics and ingredients.

Zhang teaches that one of the advantages of his invention is that it obviates the need to remove the cream from the skin by extensive washing or cleansing of the skin. When the desired anesthetic effect is achieved, the solid gel is peeled off the skin area, leaving virtually no residual mess on the skin. The skin area is anesthetized and if desired can be subjected to a medical treatment or procedure (col. 9, line 45 – col. 10, line 9).

Zhang teaches drug formulations and delivery systems that can be applied to and then peeled off the skin and/or off compromised human body surfaces after the drug delivery is achieved. There is no significant distinction observed between the instant method and the methods of the prior art since Zhang explicitly teaches methods of drug delivery comprising active ingredients, such as dermal-treating drugs, particularly, collagenase in combination with fluid carriers and conversion agents wherein the formulation can be cleanly peeled off the skin.

Thus, given the explicit teachings of Zhang delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang (U.S. Pat. No. 6,528,086 B2) as applied to claims 1-8, 10-16 and 30-32 above and further in view of Tipton *et al.* (U.S. Pat. No. 5,632,727).

The teachings of Zhang are discussed above. Zhang teaches vitamins, such as vitamins A & D (see column 11, lines 32-33). Zhang does not teach *Vitamin E.*

***Tipton et al.* ('727)** teach a biodegradable film dressing and methods of using the film dressing to treat injured tissues and deliver biologically active agents wherein the film comprises vitamins, such as vitamin E (see reference column 10, lines 17-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the vitamin E as taught by Tipton *et al.* within the delivery formulations of Zhang. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Tipton *et al.* explicitly teach that suitable and effective vitamins that are beneficial in their formulation include vitamin E. The expected result would be an optimally-enhanced formulation for the treatment of skin conditions.

Prior Art made of record, not relied upon and deemed relevant by the Examiner:

US Patent No. 5,446,070 *Mantelle* 08/1995

US Patent No. 4,937,078 *Mezei et al.* 06/1990

Response to Arguments

Applicant's arguments filed 04/12/07 have been fully considered and were found partially persuasive.

- **35 U.S.C. §112, 1st paragraph rejection**:

Applicant argued, "Applicant respectfully asserts that the specification is sufficient to teach one of skill in the art would to make and use the claimed invention. Importantly, Applicant's disclosure states, "a composition is provided to treat wounds or hypertrophic scars so as to prevent scar formation or reduce the size of the scars and improve the appearance thereof." See Applicant's Specification at page 16, line 24 through page 17, line 1 (emphasis added). This section of Applicant's disclosure goes on to disclose useful compositions for preventing scar formation, stating "[i]n this form of the invention, an active ingredient in the form of a steroid is added to the film-forming carrier." See Applicant's specification at page 17, lines 1-19. The specification continues, the composition "can be readily and directly applied to the affected tissue. The composition forms a solid, tangible film as above described which maintains the steroid active ingredient juxtaposed to the wound or scar tissue and provides an advantageous and continuous healing effect of the steroid." See Applicant's Specification at page 17, lines 10-14. Nevertheless, the Examiner states, "[t]he working examples are insufficient to establish the method of treating healed wounds to 'prevent' scarfing." See Office Action at page 4, first paragraph. However, Applicant notes that, "[c]ompliance with the enablement requirement.., does not turn on whether an example is disclosed." See M.P.E.P. §2164.02, Eighth Edition, Rev. 5, Aug. 2006 at page 2100-189. Again, Applicant respectfully asserts that in light of the specification one of skill in the art would know how to make and use the claimed invention."

Applicant's arguments have been considered, but were not persuasive. It remains the position of the Examiner that the instant specification, while being enabling for "reducing scarring and/or improving the appearance of scars", is not enabling for the "prevention" of scarring. It would require undue and painstaking experimentation to determine which particular process steps and combination of elements would be required to reduce scarring and/or improve scar appearance, with the prevention of scarring being even less likely. Prior art formulations, which utilize similar process steps and components as that claimed by Applicant, recognize and teach systems and treatment methods for dermal applications, but not the "*prevention*" of dermal conditions and disorders. Thus, it is questionable as to how the instant invention achieves "prevention" of scarring. It is suggested that the term "prevention" be deleted to overcome this rejection.

- **Non-statutory double patenting rejection**:

Applicant argued, "It is the Applicant's intention to allow the '183 Application to go abandoned. As such, this rejection is moot."

Applicant's arguments have been considered and were found persuasive. Accordingly, the non-statutory double patenting rejection of claims 1, 5-16, 30 and 31 has been withdrawn.

- **35 U.S.C. §103(a) rejection**:

Applicant argued, "Zhang is broadly directed to a method and device for dermal drug delivery. The composition is "applied to certain human body surfaces, such as skin having an abrasion, laceration or post-surgery

wound. Zhang does not disclose the application of the composition to healed wounds. Zhang does not disclose any drugs for the treatment of or reduction in appearance of scar tissue. Zhang makes no mention of treating or reducing scar tissue whatsoever. For claim 30, like claim 1, Zhang does not disclose or suggest treating a healed wound or reducing the appearance of scar tissue."

Applicant's arguments have been considered, but were not persuasive. The methods and devices taught by Zhang are explicitly employed for the treatment of dermal conditions. Particularly, the argument that "Zhang teaches application of their composition to human body surfaces such as skin having lacerations, abrasions, etc, but not healed wounds" was not persuasive since the skin conditions taught by Zhang (abrasions, lacerations, etc.) would be encompassed in and would include the "healed wounds" instantly claimed by Applicant. The term "healed wounds" is generic enough to read on various conditions, including those suggested in the Zhang patent. The methods and devices taught by Zhang are similar to the methods instantly claimed, as Zhang employs process steps as claimed and uses similar components to treat dermal conditions as that desired by Applicants. The formulations of Zhang can be applied to skin and compromised surfaces and can be peeled off after therapeutic effect is achieved. Applicant's argument that "Zhang does not disclose any drugs for the treatment of, or reduction of appearance of scar tissue" was not persuasive, since the methods and devices taught by Zhang would ultimately yield a reduction in scarring, as Zhang teaches various dermatological agents for the promotion of wound healing, thus resulting in reduced scar appearance. Applicant has not established a patentable distinction between the teachings of the prior art and that of the instant invention. The prior art vividly teaches methods for dermal drug delivery for application on human skin that is essentially similar to the methods claimed by Applicant.

Regarding the rejection of claim 9 ((Zhang in view of Tipton ('727)), Applicant argued, "Tipton does not make up for the deficiency of Zhang. Tipton does not teach or suggest application to a healed wound for reducing the appearance of scar tissue."

Applicant's arguments were not persuasive. As noted above, Zhang provides for methods for dermal drug delivery comprising similar steps and elements as that of the instant invention. The formulations of Zhang would yield reduction in appearance of scar tissue since Zhang provides for compositions having dermatological therapeutic agents that would promote wound healing and thus, reduce scar appearance. Tipton was relied upon solely for the teaching of Vitamin E, and thus, remedies this only deficiency of Zhang.

It remains the position of the Examiner that Applicants have not established a patentable distinction between the prior art and the instant invention, nor have any unexpected results been demonstrated through the instant invention. The instant claims remain generic enough to read on the teachings of the prior art delineated above. Thus, Applicant's arguments were not rendered persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

July 5, 2007

HUMERA N. SHEIKH
PRIMARY EXAMINER

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